

MAY 30 2003

K03 1406 1 of 2

## SECTION 2 – 510(k) SUMMARY

### EXOJET Tissue Management System

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**Submitter's Name and Address:**

Mitek Worldwide  
a division of ETHICON Inc.  
a Johnson & Johnson Company  
249 Vanderbilt Avenue  
Norwood, MA 02062

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**Contact Person**

Sergio J. Gadaleta, Ph.D.  
Manager, Regulatory Affairs  
Mitek Worldwide  
a division of ETHICON Inc.  
a Johnson & Johnson Company  
249 Vanderbilt Avenue  
Norwood, MA 02062  
Telephone: 781-251-2018  
Facsimile: 781-278-9578  
e-mail: [sgadalet@ethus.jnj.com](mailto:sgadalet@ethus.jnj.com)

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**Name of Medical Device**

Classification Name: Arthroscope and Accessories  
Common/Usual Name: Arthroscope and Accessories  
Proprietary Name: EXOJET Tissue Management

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**Substantial Equivalence**

EXOJET Tissue Management System is substantially equivalent to:

Hydrocision ARTHROJET System with Cautery and TurboBurr  
K020688, K002764, K993009, K982266 – Distributed by Mitek  
Worldwide a division of Ethicon, Inc., a Johnson & Johnson  
Company, 249 Vanderbilt Avenue, Norwood, MA 02062 and  
manufactured by Hydrocision Inc., 100 Burt Road G01, Andover,  
MA 01810.

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**Device Classification**

Arthroscopes and accessories are classified by FDA as a Class II  
Medical Devices under the generic category of Arthroscope  
(reference 21 CFR §888.1100), product code HRX.

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**Device Description**

Mitek's EXOJET Tissue Management System consists of reusable power control unit; sterile, disposable pump cartridge and tubing assembly; and sterile, disposable handpieces. It provides the same functions as the predicate device including cutting, evacuation, and electrocauterization. The various handpieces are designed to provide the additional functions of cutting, drilling, reaming, decorticating, and smoothing of bone. The handpiece includes a rotating burr, which is driven by a liquid-jet driven motor. It is also available with a variety of burrs and drills.

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**Indications for Use**

The Mitek EXOJET\* system is indicated for orthopedic surgical procedures where the cutting and removal of soft tissue, hard tissue, or bone is required, with control of bleeding during those procedures as needed. Specific functions include cutting, ablation, and shaping of soft tissue, and decorticating, removing, and smoothing of bone and other bone-related tissue in a variety of small and large joint arthroscopic procedures.

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**Safety**

Biocompatibility studies have demonstrated the EXOJET Tissue Management System to be non-toxic, non-irritating, non-sensitizing, and non-cytotoxic.

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MAY 30 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Sergio J. Gadaleta, Ph.D.  
Manager, Regulatory Affairs  
Mitek Worldwide  
a division of Ethicon, Inc.  
249 Vanderbilt Avenue  
Norwood, Massachusetts 02062

Re: K031406

Trade/Device Name: EXOJET Tissue Management System  
Regulation Number: 21 CFR 888.1100  
Regulation Name: Arthroscope  
Regulatory Class: II  
Product Code: HRX  
Dated: May 2, 2003  
Received: May 20, 2003

Dear Dr. Gadaleta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

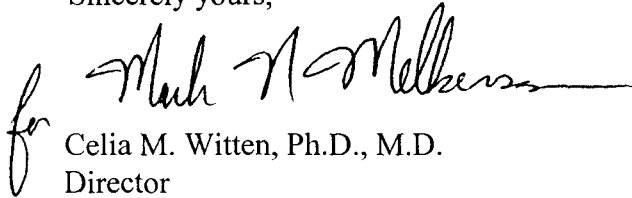
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

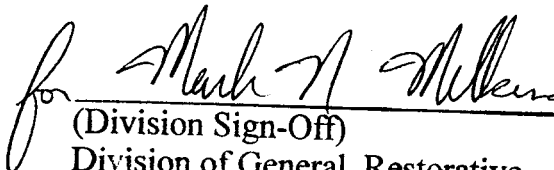
## INDICATIONS FOR USE

510(k) Number (if known): K031406

Device Name: **EXOJET Tissue Management System**

Indications for Use:

The Mitek EXOJET\* system is indicated for orthopedic surgical procedures where the cutting and removal of soft tissue, hard tissue, or bone is required, with control of bleeding during those procedures as needed. Specific functions include cutting, ablation, and shaping of soft tissue, and decorticating, removing, and smoothing of bone and other bone-related tissue in a variety of small and large joint arthroscopic procedures.

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K031406

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

or

Over-the-Counter Use \_\_\_\_\_